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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,756	12/21/2005	Richard E Musty	B0192.70062US00	1614
23628 7590 12/05/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER CLAYTOR, DEIRDRE RENEE	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			12/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,756	<b>Applicant(s)</b> MUSTY ET AL.	
	<b>Examiner</b> Renee Claytor	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14, 15 and 18-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-15, 18-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's response filed on 9/4/2007 is acknowledged. Applicants have cancelled claims 1-13 and 16-17 and added new claims 20-28. Accordingly, claims 14-15 and 18-28 are being examined herein.

Applicants have pointed out the Declaration contained in the international phase of the application, which includes the address of each inventor as well as the signature of each inventor. Therefore, the objection to the Oath and Declaration is withdrawn.

Because Applicants have cancelled claims 1-11 and 13, the 35 USC 112 second paragraph rejection is hereby withdrawn. Further, the 35 USC 103(a) rejection over claims 1-13 over Travis (US Patent 6,541,510) in view of Turner et al. (J Clin Pharmacol. 1981; 21: 283S-291S) is also withdrawn.

Applicant's arguments over the 35 USC 103(a) rejection over claims 14-19 which were rejected over Travis (US Patent 6,541,510) in view of Turner et al. (J Clin Pharmacol. 1981; 21: 283S-291S) and further in view of Brooke et al. (US Patent 6,328,992) have been fully considered and are not found persuasive. Applicants argue that neither Travis or Turner teach or suggest the use of cannabichromene for the treatment of a mood disorder. Applicants argue further that the disclosure of Brooke et al. does not specifically teach that cannabichromene is useful in the treatment of mood disorders but suggests that cannabinoids have been used in this way.

In response to the above argument, Brooke et al. teaches that several medicinal uses have been found for the active ingredients of cannabis, which includes cannabichromene. Brooke et al. further teaches that the medicinal uses include stress

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and depression (see Col. 1, lines 24-33). Brooke et al. teaches other disorders in which it is well known in the art that cannabis and its active ingredients are useful for treating, including nausea and pain associated with cancer and chemotherapy and AIDS.

Therefore, it would be obvious to a person of ordinary skill in the art that active ingredients of cannabis are a useful treatment for a variety of disorders, which include mood disorders such as stress and/or depression.

Because of Applicants amendments the claims, the following modified rejections are being made.

### ***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-15, 18-28 rejected under 35 U.S.C. 103(a) as being unpatentable over Brooke et al. (US Patent 6,328,992) in view of Travis (US Patent 6,541,51) and Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

Brooke et al. teach that medicinal uses, such as depression, have been found for the active ingredients of cannabis, including cannabichromenes (meeting the limitation of claims 14-15; Col. 1, lines 23-33).

Brooke et al. does not teach a cannabichromene compound of the same structural formula as Formula (I) in claims 14 and 20-24, that the cannabichromene

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compound is an extract of at least one cannabis plant as claimed in claims 18 and 25-27 or the route of administration.

Travis teaches pharmaceutical compositions comprised of cannabichromene compounds of the general formula (I), wherein  $R^1$  is OH,  $R^2$  is H,  $R^3$  is a  $C_{5-12}$  alkyl, Q is O,  $R^6$  is  $C_{1-6}$  alkyl, and  $R^{12}$  and  $R^{12'}$  are  $C_{1-6}$  alkyl (meeting the limitations of claims 1 and 20-24; Col. 2, lines 21, 25, 55-56; Col. 3, lines 24, 35, 39, 64; Col. 4, line 2). The compositions are further obvious over general formula (I) when  $R^3$  is  $C_3H_7$  of claims 20-21 because the difference between  $C_3H_7$  and  $C_5H_{11}$  (as taught by Travis) differ in only two carbons and are considered analogous over each other. Travis further teaches that the alkyl groups of  $R_3$  can be straight chained (meeting the limitations of claim 22; paragraph 0102). Travis further teaches that the composition includes a suitable carrier and routes of administration that encompass claims 19 and 28 (paragraph 0106).

Turner et al. teach that cannabichromene is a crude drug made from cannabis plants and is one of the most abundant naturally occurring cannabinoids (meeting the limitations of claims 18 and 25-27; see Introduction).

Accordingly, it would have been obvious to a person of ordinary skill in the art at the time of the invention, to treat mood disorders such as depression with cannabichromene compounds because of the teachings of Brooke et al. that cannabichromenes are useful in treating such disorders as depression. It would have further been obvious to use the cannabichromene composition taught by Travis and Turner et al. to treat depression, because Travis and Turner et al. teach cannabichromene compositions that are useful as pharmaceutical compositions. One

would have been motivated to use the cannabichromene compositions taught by Travis and Turner et al. to treat depression with a reasonable expectation of success because Brooke et al. teaches that cannabichromenes show medicinal use in treating depression.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

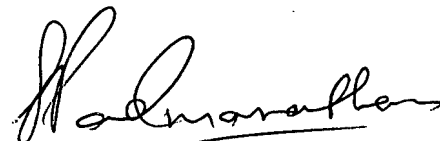
**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER